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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,808	01/27/2000	BJORN H. LINDQVIST	100084.410	2109
23117	7590	08/24/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			WESSENDORF, TERESA D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/331,808	LINDQVIST ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	T. D. Wessendorf	1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21,22,24-29,31,32,34-36,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,22,24-29,31,32,34-36,39 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/04 has been entered.

***Status of Claims***

Claims 21, 22, 24-29, 31-32, 34-36 and 39-40 are pending in the application and under consideration.

Claims 1-20, 23, 30, 33 and 37-38 have been cancelled.

The rejection of the claims under 35 USC 112, second paragraph no longer applies in part with the cancellation and amendment to the claims and in part due to applicants' arguments.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 31 and 32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed DNA molecule comprising the recited components therein would read on naturally occurring phages.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by either Liu et al (Virology, 1996) or applicants' disclosure of known prior art.

Liu et al discloses at page 158 under the Materials and Methods section up to page 150, col. 1 a DNA cis-proteins comprising of a plasmid containing a mutated cis-proteins and fragments of the P2A genes which had been amplified by DNA primers as shown in Fig 1.

Applicants at page 10 admit that ".....cis-acting proteins include the family of replication proteins..... such as equivalent proteins from phage 186 (Sivaprasad et al., 1990, J. Mol. Biol. 213, p449-463), HPI (Esposito et al., 1996, Nucl. Acids Res. 24, p2360- 2368) and PSP3 (Bullas et al., 1991, Virology, 185, p918- 921)....."

The claimed DNA molecule is therefore fully met by each of the references above.

Claims 21,22, 24, 26, 27, 28, 31, 34-36 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Maruyama et al (USP 5,627,024).

Maruyama et al discloses at col. 8, line 62 up to col. 9, line 29 a DNA lambdoid phage particles that are about half protein and half DNA. The mature capsule of lambdoid phage is comprised of a morphologically distinct head and tail. Each phage particle

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contains one double-stranded DNA molecule capable of replication that is encapsulated in an icosahedral head from which projects a tubular tail. The bacteriophage head and tail are assembled separately and then together to form a phage particle capable of infecting and replicating in a suitable host. The bacteriophage head encapsulates the phage genome. The finished lambdoid head contains amino acid residue sequences encoded by six of the twelve genes required for its assembly. The assembled lambdoid head thus contains gene products of six genes and eight types of polypeptides refer to a cleavage product. The eight types polypeptides are assembled on the surface of the lambda head and provide the means for display of a foreign polypeptide in a surface-accessible manner on the surface of the lambdoid phage particle. Maruyama discloses at col. 6, lines 48-52 that the phages are cis. Cis refers to when the phage genome contains a second cistron for the expression of heterosubunits, (1) other than the fusion protein subunit or (2) supplementing the amounts of fusion protein subunit; and for supplemental expression of the homomeric subunit in soluble form. At col. 40, line 56 up to col. 41, line 36, the methods for the preparation of a library of DNA molecules having one or more cistrons for expressing a fusion protein of this invention is described. The multiple cistrons are operatively linked at relative locations on the DNA

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molecule such that the cistrons are under the transcriptional control of a single promoter. The phrase "operatively linked" means the sequences or segments have been covalently joined. Each multicistronic molecule is capable of expressing first, second, and optionally third polypeptides from first, second, and optional third overlapping cistrons, respectively, that can assemble to form, in a suitable host, a multimeric receptor on the surface of a lambdoid phage particle. Murayama further discloses at col. 43, line 43 up to col. 45, line 2 a method for screening proteins of the phage particles. Also, the method of assaying (claim 36) is disclosed at col. 45, line 5 up to col. 48, line 47. The method for detecting the presence of a preselected target in a sample is likewise disclosed by Murayama. The method comprises: a) admixing a sample containing a preselected target with a recombinant lambdoid bacteriophage, wherein the preselected polypeptide defines a biologically active ligand or receptor able to bind the preselected target, under binding conditions sufficient for the target-binding bacteriophage to bind the target and form a target-ligand or receptor complex; b) detecting the presence of the complex, and thereby the presence of the preselected target. See further the claims. Accordingly, the processes described by Murayama fully meet the claimed broad processes.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21 22, 24-29, 31-32, 34-36 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murayama in view of Liu et al (Virology, 1996).

Murayama is discussed above. Murayama does not disclose the cis-acting protein as P2A protein (as in claim 25) or its modified form (as in claim 29) or X174. However, Liu et al discloses at page 158 under the Materials and Methods section up to page 150, col. 1 a cis-proteins comprising P2A genes. Liu discloses phage x174 is the best studied system for rolling circle replication commonly used among circular replicons of different origins. P2A is believed to follow a similar mode of replication. The A protein is transferred to the progeny' strand to initiate a new round of replication. It would have been



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obvious to one having ordinary skill in the art at the time the invention was made to use x174 in the method of Murayama as taught by Liu. x174 is the best studied system for replicons of the rolling circle replication. A well-studied system will aid in the elimination of some unpredictable effect of a lesser known DNA phages in the study of these viruses.

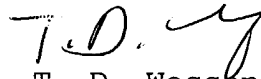
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw

August 21, 2004